10-31-00

A

Practitioner's Docket No. U 013032-6 ***PATENT***

Preliminary Classification:
Proposed Class:
Subclass:
NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P. Section 601, 7th ed.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Optional Customer No. Bar Code

00140
PATENT TRADEMARK OFFICE

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of
Inventor(s): Peter Bennett Duff WHYTE

WARNING: *37 C.F.R. Section 1.41(a)(1) points out:*

"(a) A patent is applied for in the name or names of the actual inventor or inventors.

(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.63, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(I) is filed supplying or changing the name or names of the inventor or inventors."

For (title): A FOOD COMPOSITION AND METHOD OF USING SAME

CERTIFICATION UNDER 37 C.F.R. 1.10*
*(Express Mail label number is **mandatory**.)*
(Express Mail certification is optional.)

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on this date OCTOBER 27, 2000, in an envelope as "Express Mail Post Office to Addressee", m ailing Label Number EL699732416US, addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

BARBARA D. SANTIAGO
(type or print name of person mailing paper)

Barbara D Santiago
Signature of person mailing paper

WARNING: *Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*

****WARNING:*** *Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).*
*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

EL 6 9 9 7 3 2 4 1 6 US

1. Type of Application

This new application is for a(n)

(check one applicable item below)

[X] Original (nonprovisional)
[ ] Design
[ ] Plant

WARNING: ***Do not*** *use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.*

WARNING: ***Do not*** *use this transmittal for the filing of a provisional application.*

NOTE: If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

[ ] Divisional.
[X] Continuation.
[ ] Continuation-in-part (C-I-P).

2. Benefit of Prior U.S. Application(s) (35 U.S.C. Sections 119(e), 120, or 121)

NOTE: A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. Section 112. Each prior application must also be:

(I) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) Complete as set forth in Section 1.51(b); or

(iii) Entitled to a filing date as set forth in Section 1.53(b) or Section 1.53(d) and include the basic filing fee set forth in Section 1.16; or

(iv) Entitled to a filing date as set forth in Section 1.53(b) and have paid therein the processing and retention fee set forth in Section 1.21(l) within the time period set forth in Section 1.53(f).

37 C.F.R. Section 1.78(a)(1).

NOTE *If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.*

WARNING: *If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-I-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.*

WARNING: *When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional application **must** be filed prior to the Saturday, Sunday, or Federal holiday within the District of Columbia. See 37 C.F.R. Section 1.78(a)(3).*

[X] The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

3. Papers Enclosed

A. Required for Filing Date under 37 C.F.R. Section 1.53(b) (Regular) or 37 C.F.R. Section 1.153 (Design) Application

__34__ Pages of Specification
__4__ Pages of Claims
__5__ Sheets of Drawing

WARNING: ***DO NOT** submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to Section 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. 1.84, see Notice of March 9, 1988 . (1990 O.G. 57-62).*

NOTE: *"Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page. . ." 37 C.F.R. Section 1.84(c)).*

(complete the following, if applicable)

[ ] The enclosed drawing(s) are in color, and there is also attached a "PETITION TO ACCEPT COLOR DRAWING(S)." 37 C.F.R. Section 1.84(b).

[X] Formal
[ ] Informal

B. Other Papers Enclosed

____ Pages of declaration and power of attorney
__1__ Pages of Abstract
____ Other

4. Additional Papers Enclosed

[ ] Amendment to claims

[ ] Cancel in this applications claims _____ before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

[ ] Add the claims shown on the attached amendment. (Claims added have been numbered consecutively following the highest numbered original claims.)

[X] Preliminary Amendment
[ ] Information Disclosure Statement (37 C.F.R. Section 1.98)
[ ] Form PTO-1449 (PTO/SB/08A and 08B)
[ ] Citations
[ ] Declaration of Biological Deposit
[ ] Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.
[ ] Authorization of Attorney(s) to Accept and Follow Instructions from Representative
[ ] Special Comments
[ ] Other

5. Declaration or Oath (including power of attorney)

NOTE: A newly executed declaration is not required in a continuation or divisional application provided the prior nonprovisional application contained a declaration as required, the application being filed is by all or fewer than all the inventors named in the prior application, there is no new matter in the application being filed, and a copy of the executed declaration filed in the prior application (showing the signature or an indication thereon that it was signed) is submitted. The copy must be accompanied by a statement requesting deletion of the names of person(s) who are not inventors of the application being filed. If the declaration in the prior application was filed under Section 1.47 then a copy of that declaration must be filed accompanied by a copy of the decision granting Section 1.47 status or, if a nonsigning person under Section 1.47 has subsequently joined in a prior application, then a copy of the subsequently executed declaration must be filed. See 37 C.F.R. Section 1.63(d)(1)-(3).

NOTE: A declaration filed to complete an application must be executed, identify the specification to which it is directed, identify each inventor by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and the residence, post office address and country of citizenship of each inventor, and state whether the inventor is a sole or joint inventor. 37 C.F.R. Section 1.63(a)(1)-(4).

NOTE: A The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.62, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(I) is filed supplying or changing the name or names of the inventor or inventors. 37 C.F.R. Section 1.41(a)(1).

[ ] Enclosed

Executed by

(check **all** *applicable boxes)*

[ ] inventor(s).
[ ] legal representative of inventor(s). 37 C.F.R. Section 1.42 or 1.43.
[ ] joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

[ ] This is the petition required by 37 C.F.R. Section 1.47 and the statement required by 37 C.F.R. Section 1.47 is also attached. See item 13 below for fee.

[X] Not Enclosed.

NOTE: *Where the filing is a completion in the U.S. of an International Application, or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.*

[ ] Application is made by a person authorized under 37 C.F.R. 1.41 on behalf of *all* the above named inventor(s).

(The declaration or oath, along with the surcharge required by 37 C.F.R. Section 1.16(e), can be filed subsequently).

[ ] Showing that the filing is authorized.
(not required unless called into question. 37 C.F.R. Section 1.41(d))

6. Inventorship Statement

WARNING: *If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.*

The inventorship for all the claims in this application are:

[ ] The same.

or

[ ] Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,
[ ] is submitted.
[ ] will be submitted.

7. Language

NOTE: An application including a signed oath or declaration may be filed in a language other than English. An English translation of the non-English language application and the processing fee of $130.00 required by 37 C.F.R. Section 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 C.F.R. Section 1.52(d).

[X] English
[ ] Non-English

[ ] The attached translation includes a statement that the translation is accurate. 37 C.F.R. Section 1.52(d).

8. Assignment

[X] An assignment of the invention to NORTHFIELD LABORATORIES PTY. LTD.,

[ ] is attached. A separate [ ] "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or [ ] FORM PTO 1595 is also attached.
[X] will follow.
[ ] has been recorded at Reel _____, Frame _____ on _____

NOTE: "If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment" Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: *A newly executed "STATEMENT UNDER 37 C.F.R. Section 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.*

9. Certified Copy

Certified copy(ies) of application(s)

Country	Appln. no.	Filed
Country	Appln. no.	Filed
Country	Appln. no.	Filed

from which priority is claimed
[ ] is (are) attached.
[ ] will follow.
[ ] was filed in parent application _____

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 C.F.R. Section 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 C.F.R. Section 1.16)

A. [X] Regular application

CLAIMS AS FILED

Claims	Number Filed	Basic Fee Allowance	Number Extra	Rate	Basic Fee 37 C.F.R. Section 1.16(a) $710.00
Total Claims (37 C.F.R. Section 1.16(c))	27	- 20 =	x	$ 18.00	$126.00
Independent Claims (37 C.F.R. Section 1.16(b))	2	- 3 =	x	$ 80.00	
Multiple Dependent Claim(s), if any (37 C.F.R. Section 1.16(d))			+	$270.00	

[ ] Amendment cancelling extra claims is enclosed.
[X] Amendment deleting multiple-dependencies is enclosed.
[X] Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 C.F.R. Section 1.16(d).

Filing Fee Calculation $_____

B. [ ] Design application
($320.00--37 C.F.R. Section 1.16(f))
Filing Fee Calculation $_____

C. [ ] Plant application
($490.00--37 C.F.R. Section 1.16(g))
Filing Fee Calculation $_____

11. Small Entity Statement(s)

[ ] Statement(s) that this is a filing by a small entity under 37 C.F.R. Section 1.9 and 1.27 is (are) attached.

WARNING: *"Status as a small entity must be specifically established in each application or patent in which the status is available and desired. Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. The refiling of an application under Section 1.53 as a continuation, division, or continuation-in-part (including a continued prosecution application under Section 1.53(d)), or the filing of a reissue application requires a new determination as to continued entitlement to small entity status for the continuing or reissue application. A nonprovisional application claiming benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) of a prior application, or a reissue application may rely on a statement filed in the prior application or in the patent if the nonprovisional application or the reissue application includes a reference to the statement in the prior application or in the patent or includes a copy of the statement in the prior application or in the patent and status as a small entity is still proper and desired. The payment of the small entity basic statutory filing fee will be treated as such a reference for purposes of this Section." 37 C.F.R. Section 1.28(a)(2).*

WARNING: *"Small entity status must not be established when the person or persons signing the . . . statement can **unequivocally** make the required self-certification." M.P.E.P. Section 509.03, 6th ed., rev. 2, July 1996 (emphasis added).*

(complete the following, if applicable)

[ ] Status as a small entity was claimed in prior application _____, filed on _____ from which benefit is being claimed for this application under:

35 U.S.C. Section
- [ ] 119(e) - provisional,
- [ ] 120 - continuation,
- [ ] 121 divisional,
- [ ] 365(c) - PCT,

and which status as a small entity is still proper and desired.

[ ] A copy of the statement in the prior application is included.

Filing Fee Calculation (50% of **A**, **B** or **C** above) $_____

NOTE: Any excess of the full fee paid will be refunded if a small entity status is established refund request are filed within 2 months of the date of timely payment of a full fee. The two-month period is not extendable under Section 1.136. 37 C.F.R. Section 1.28(a).

12. Request for International-Type Search (37 C.F.R. Section 1.104(d))

(complete, if applicable)

[ ] Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made at This Time

[X] Not Enclosed

[X] No filing fee is to be paid at this time.
(This and the surcharge required by 37 C.F.R. Section 1.16(e) can be paid subsequently.)

[ ] Enclosed

[ ] Filing fee $_____

[ ] Recording assignment
($40.00; 37 C.F.R. Section 1.21(h))
(See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION.") $_____

[ ] Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached
($130.00; 37 C.F.R. Sections 1.47 and 1.17(I)) $_____

[ ] For processing an application with a specification in a non-English language
($130.00; 37 C.F.R. Sections 1.52(d) and 1.17(k)) $_____

[ ] Processing and retention fee
($130.00; 37 C.F.R. Sections 1.53(d) and 1.21(l)) $_____

[ ] Fee for international-type search report
($40.00; 37 C.F.R. Section 1.21(e)) $_____

NOTE: 37 C.F.R. Section 1.21(l) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 C.F.R. Section 1.53(f) and this, as well as the changes to 37 C.F.R. Section 1.53 and 1.78(a)(1), indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of Section 1.21(l) must be paid, within 1 year from notification under Section 53(f).

Total Fees Enclosed $_____

14. Method of Payment of Fees

[ ] Check in the amount of $_____.

[ ] Charge Account No. _____ in the amount of $_____.
A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. Section 1.22(b).

15. Authorization to Charge Additional Fees

WARNING: *If no fees are to be paid on filing, the following items should not be completed.*

WARNING: *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.*

[ ] The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No._____.

[ ] 37 C.F.R. Section 1.16(a), (f) or (g) (filing fees)

[ ] 37 C.F.R. Section 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. Section 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

[ ] 37 C.F.R. Section 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

[ ] 37 C.F.R. Section 1.17(a)(1)-(5) (extension fees pursuant to Section 1.136(a).

[ ] 37 C.F.R. Section 1.17 (application processing fees)

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under Section 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in Section 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. Section 1.136(a)(3).

[ ] 37 C.F.R. Section 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. Section 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. Section 1.311(b)).

NOTE: 37 C.F.R. Section 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . issue fee." From the wording of 37 C.F.R. Section 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions as to Overpayment

NOTE: ". . . Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. Section 1.26(a).

[X] Credit Account No. 12-0425.

[ ] Refund

SIGNATURE OF PRACTITIONER

Reg. No. 25,858

William R. Evans
(type or print name of practitioner)

Tel. No.: (212) 708-1930

P.O. Address

Customer No.:

c/o Ladas & Parry
26 West 61st Street
New York, N.Y. 10023

[X] **Incorporation by reference of added pages**

(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)

[X] Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Number of pages added 5

[ ] Plus Added Pages for Papers Referred to in Item 4 Above

Number of pages added _____

[ ] Plus added pages deleting names of inventor(s) named on prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application.

Number of pages added _____

[ ] Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added _____

[ ] **Statement Where No Further Pages Added**

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item)

[ ] This transmittal ends with this page.

Practitioner's Docket No. U 013032-6 *PATENT*

ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

NOTE: See 37 CFR 1.78.

17. Relate Back

WARNING: *If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.*

(complete the following, if applicable)

[X] Amend the specification by inserting, before the first line, the following sentence:

A. 35 U.S.C. 119(e)

NOTE: "Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number)." 37 C.F.R. § 1.78(a)(4).

[ ] "This application claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:	**FILING DATE**
_____/_____	_____
_____/_____	_____
_____/_____	_____

and incorporates the same by reference."

B. 35 U.S.C. 120, 121 and 365(c)

NOTE: "Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. . . . Cross-references to other related applications may be made when appropriate." (See § 1.14(a)). 37 C.F.R. § 1.78(a)(2).

[X] "This application is a

[X] continuation

[ ] continuation-in-part

[ ] divisional

of

[ ] application number _____ filed on _____,
[ ] which is
[X] International Application PCT/AU99/00317 filed on April 30, 1999 and which designated the U.S.,
claims the benefit thereof and incorporates the same by reference."

NOTE: The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

NOTE: The deadline for entering the national phase in the U.S. for an international application was clarified in the Notice of April 28, 1987 (1079 O.G. 32 to 46) as follows:

"The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of § 1.494 and paragraph (i) of § 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application."

[ ] "The nonprovisional application designated above, namely application _____/_____, filed _____, claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:	**FILING DATE**
_____/_____	_____"
_____/_____	_____"
_____/_____	_____"
_____/_____	_____

[ ] Where more than one reference is made above please combine all references into one sentence.

18. Relate Back—35 U.S.C. 119 Priority Claim for Prior Application

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17B, in turn itself claim(s) foreign priority(ies) as follows:

Country	Appln. no.	Filed
AU	PP 3271	30 APRIL 1998

The certified copy(ies) has (have)

[ ] been filed on _____, in prior application _____, which was filed on _____.

[ ] is (are) attached.

WARNING: *The certified copy of the priority application that may have been communicated to the PTO by the International Bureau may not be relied on without any need to file a certified copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore, such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications that have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).*

19. Maintenance of Copendency of Prior Application

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).

A. [ ] Extension of time in prior application

*(This item **must** be completed and the papers filed **in the prior application,** if the period set in the prior application has run.)*

[ ] A petition and fee extends the term in the pending **prior** application until _____.

[ ] A **copy** of the petition filed in prior application is attached.

B. [ ] Conditional Petition for Extension of Time in Prior Application

[ ] A conditional petition for extension of time is being filed in the pending **prior** application.

[ ] **A copy** of the conditional petition filed in the prior application is attached.

C. [ ] No extension is necessary in Prior Application
[ ] Issue Fee paid _____

20. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

(complete applicable item (a), (b) and/or (c) below)

(a) [ ] This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are

[ ] the same.

[ ] less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:

_____

(type name(s) of inventor(s) to be deleted)

(b) [ ] This application discloses and claims additional disclosure by amendment and a new declaration or oath is being filed. With respect to the prior application, the inventor(s) in this application are

[ ] the same.

[ ] the following additional inventor(s) have been added:

_____

(type name(s) of inventor(s) to be deleted)

(c) [ ] The inventorship for all the claims in this application are

[ ] the same.

[ ] not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made

[ ] is submitted.
[ ] will be submitted.

21. Abandonment of Prior Application *(if applicable)*

[ ] Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation-in- part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

22. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

WARNING: *"The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." MPEP, § 706.07(b).*

NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.

(check the next item, if applicable)

[ ] There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

23. Small Entity (37 CFR § 1.28(a))

[ ] Applicant has established small entity status by the filing of a statement in parent application _____ on _____.

[ ] A copy of the statement previously filed is included.

WARNING: *See 37 CFR § 1.28(a).*

24. NOTIFICATION IN PARENT APPLICATION OF THIS FILING

[ ] A notification of the filing of this
(check one of the following)

[ ] continuation

[ ] continuation-in-part

[ ] divisional

is being filed in the parent application, from which this application claims priority under 35 U.S.C. § 120.

Practitioner's Docket No. U 013032-6 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Peter Bennett Duff WHYTE

For: A FOOD COMPOSITION AND METHOD OF USING SAME

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

Please amend the above identified application as follows:

IN THE CLAIMS :

Claim 3, line 1: Delete "or 2"

Claim 4, line 1: Delete "claims 2 or 3" and replace therefor --claim 2--

Claim 8, lines 1-2: Delete "any one of claims 5 to 7" and replace therefor --claim 5–

Claim 11, line 3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor --claim 1--

Claim 12, lines 2-3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor

--claim 1--

Claim 13, lines 2-3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor

--claim 1--

CERTIFICATE UNDER 37 1.10

I hereby certify that this paper is being deposited with the United States Postal Service on this date OCTOBER 27, 2000 in an envelope as "EXPRESS MAIL POST OFFICE TO ADDRESSEE" Mailing Label Number EL699732416US addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231

BARBARA D. SANTIAGO
(Type or print name of person mailing paper)

Barbara D. Santiago
(Signature of person mailing paper)

NOTE: Each paper or fee referred to as enclosed herein has the number of the "EXPRESS MAIL" mailing label place thereon prior to mailing 37 CFR 1.16(b).

EL 699732416 US

Claim 14, line 3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor --claim 1--

Claim 15, lines 2-3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor

--claim 1--

Claim 16, lines 2-3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor

--claim 1--

Claim 17, line 3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor --claim 1--

Claim 19, line 3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor --claim 1--

Claim 20, line 3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor --claim 1--

Claim 21, line 3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor --claim 1--

Claim 22, lines 2-3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor

--claim 1--

Claim 23, lines 2-3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor

--claim 1--

Claim 24, line 3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor --claim 1--

Claim 25, line 3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor --claim 1--

Claim 26, lines 2-3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor

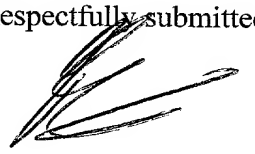
--claim 1--

Claim 27, line 3: Delete "any one of claims 1 to 4 or 8 to 10" and replace therefor --claim 1--

IN THE ABSTRACT

Please add the Abstract on the last separate page hereof.

Respectfully submitted,



WILLIAM R. EVANS
LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NEW YORK 10023
REG.NO.25,858 (212)708-1930

ABSTRACT

The present invention relates to a food composition preferably for changing body composition and/or physical work capacity. The invention further provides a method of improving body composition and/or physical work capacity. In an aspect of the present invention there is provided a food composition for use in changing the body composition and/or physical work capacity, said food composition including colostrum. In a preferred aspect there is provided a food composition for use in changing the body composition and/or physical factors maintained therein following fractionation of the colostrum. The food composition may additionally include casein. Preferably the casein is colostrum-derived and is maintained in the colostrum fraction following processing of the colostrum.

A FOOD COMPOSITION AND METHOD OF USING SAME

The present invention relates to a food composition preferably for changing body composition and/or physical work capacity. The invention further provides a method of improving body composition and/or physical work capacity.

Colostrum is the first milk secreted by the mammary glands at the end of pregnancy. It differs in composition to the milk produced later. Colostrum is a rich source of growth and anti-microbial factors (Donovan, S. M. and Odle, J (1994)); Foley, J. A. and Otterby, D. E. (1978); Reiter, B. (1978); Shams, D (1994)). Hyperimmune colostrum is commonly used as a source of antibodies against pathogens and has successfully been used to prevent and treat disease caused by pathogens such as rotavirus (Davidson 1989). Colostrum is known to have a role in development of the neonatal gut (Zumkeller, W (1992)) and to stimulate growth of small intestine in newborn piglets (Tungthanathanich, P. R. et al (1992)).

All growth activity cannot be explained by one or other known growth factors alone or in combination. Colostrum is a complex mix of growth factors and other bioactive substances, including (but not limited to) immunoglobulins, lactoferrin, lactoperoxidase, lysozyme, proline-rich polypeptide, and glycoproteins.

One of the many growth factors found in colostrum is IGF-1. In the bovine colostrum, the concentration is more than 20 times greater than in normal milk (Marcotty, C. F. et al (1991); Oda, S. H. et al (1989)). Bovine and human IGF-1 are very similar in composition.

Like many other growth factors, parenterally administered IGF-1 has been shown to have anabolic effects on skeletal muscles (Fryburg, D. A. et al (1995); Tomas, F. M. et al (1991)); and metabolic effects in increasing fat utilisation (Tomas, F.M. et al (1991)). Treatment of idiopathic short stature with human growth hormone relies in part on raising circulating IGF-1 levels There is no literature linking the use of orally ingested IGF-1 in colostrum and increased height However, the proteins for which IGF-1 and other growth

factors in colostrum increase synthesis is unclear and therefore the anabolic and metabolic effects caused by these factors are not clearly understood. Therefore, all growth activity in colostrum cannot be explained by IGF-1 alone or other known factors.

IGF-1 and other growth factors in their pure forms are expensive. Their use is generally confined to specific medical and pharmaceutical indications including tissue growth and repair. IGF-1 and other growth factors are generally regarded as being rapidly denatured in the gut prior to absorption. Therefore, the effects of the growth factors such as IGF-1, if denatured, would not be expected to be delivered in an active form to the blood or body tissues by an oral route.

Animal studies (Donovan S.M. (1994)) have shown absorption of up to approximately 10% of orally ingested radiolabelled IGF-1 in the first 24 hours after birth. Absorption beyond this period is markedly reduced as the gut "closes" and absorption of macromolecules stops, and as the environment in the gastrointestinal tract changes such that acid and proteolytic breakdown of proteins is more rapid.

Medical benefits of IGF-1 have been obtained via parenteral administration of human IGF. A readily obtainable and useable source of growth factors, high in IGF-1 or other growth factors which has been found suitable to change body composition and/or physical work capacity or to enhance performance in subjects wishing to obtain an improvement of the body such as athletes or for use by patients in a catabolic state/weight loss or for those experiencing fatigue has not been available, nor has there been a convenient or effective means to improve body composition or physical work capacity.

Despite the presence of IGF-1 and other growth factors in colostrum, it has not been proven that IGF-1 and/or other factors from bovine colostrum are available at an effective dose as anabolic agents in humans, nor has colostrum itself been shown or proven to act in an anabolic manner in humans. Therefore, it is generally considered that colostrum would have no benefits on body composition and/or physical work capacity if ingested by humans.

Accordingly it is an object of the present invention to overcome or at least alleviate some of the problems of the prior art.

In an aspect of the present invention there is provided a food composition for use in changing the body composition and/or physical work capacity, said food composition including colostrum.

In a preferred aspect there is provided a food composition for use in changing the body composition and/or physical work capacity, said food composition including colostrum or a fraction thereof wherein said fraction includes colostrum-derived growth factors maintained therein following fractionation of the colostrum. The food composition may additionally include casein. Preferably the casein is colostrum-derived and is maintained in the colostrum fraction following processing of the colostrum.

The term "physical work capacity" used herein is a measure of the ability to do physical work including any exercise performance, recovery after exercise and reduction of fatigue. The exercise performance may include any one of the exercises selected from the group including (but not limited to) running, walking, jumping, sprinting, knee extensions, knee flexions, squatting, lifting and kicking, resisted and non-resisted exercises and events.

The term "body composition" used herein includes those parameters used to define the make-up of the body including markers of anthropometric or metabolic change (including changes to mood state) selected from the group including (but not limited to) height, percentage body fat, fat mass, fat free mass, dietary intake, oxygen uptake (VO_2max), respiratory exchange ratio (RER), blood, serum creatine kinase (CK), lactulose: rhamnose ratio (L:Rh) intestinal permeability, blood lactate, metabolic and/or respiratory buffer capacity, connective, muscle, nervous and epithelial tissue, and mood state.

The term "changing body composition and/or physical work capacity" as used herein is a change which results in an improvement to the body. An "improvement" may be any change which is favourable for achieving a result, including the perception of an improvement. For instance, an improvement for achieving weight loss or body toning may include a reduction in body fat and an increase in fat-free mass (increased lean tissue and increased loss of fat

tissue). Preferably the ratio of fat-free mass to body fat is increased. Preferably the change is an improvement of exercise performance to achieve better athleticism or better endurance in occupational circumstances.

The food composition is preferably for use in changing, in a favourable or improved manner, the body composition and/or physical work capacity preferably in subjects wishing to obtain an improvement to the body as described above, athletes, people with physically demanding occupations or pastimes, or patients in a catabolic state/weight loss situation, or experiencing fatigue. When the food composition is administered to an athlete, it is considered that the food composition including colostrum and a carrier may have a positive effect on the athlete who is subjected to metabolic and physical stresses which normally lead to anthropometric and metabolic adaptations even without supplementation with the food composition.

The food composition may be used by any type of athlete. The athlete may be a power/strength athlete (PSA) or an endurance athlete (EA). The PSA generally undertakes strength and power training as part of their normal training programme. The EA generally undertakes programmes which enhance their ability to undertake prolonged exercise.

The food composition includes colostrum. The source of colostrum may be from any mammal. Preferably the mammal will be selected from the group including (but not limited to) the bovine, ovine, porcine, caprine or equine. More preferably, the colostrum is from the bovine. More preferably the colostrum is collected in the first few days after the end of pregnancy, preferably up to 3 or 4 days after the end of pregnancy.

The colostrum may be treated to reduce contaminants Preferably the treated colostrum has bioactivity and bioavailability close to that of untreated colostrum.

In a preferred aspect of the present invention there is provided a food composition for use in changing body composition and/or physical work capacity, said food composition including colostrum having a mixture of growth factors and a carrier.

Preferably the growth factors are colostrum-derived and may include IGF-1, preferably derived from colostrum. Pasteurisation, pH changes and some other treatments used to reduce contamination or produce colostrum products can destroy or reduce the levels of growth factors and other bioactive substances found in colostrum, and/or reduce their stability/bioavailability in the gut.

IGF-1 has anabolic effects which may contribute to increased synthesis of contractile or non-contractile proteins which leads to an increase in muscle mass. This may benefit users in terms of increasing muscular power and strength. Preferably, the food composition is for use in changing the exercise performance or physical work capacity in PSA.

However, the only published study to date which has investigated the effect of an orally administered bovine colostrum product is that by Mero, A *et al* (1997). Mero studied the effect of a liquid whey protein extract of colostrum on muscular power as measured by vertical jump performance and failed to find any positive effect on performance. Mero's result supports the commonly held view that orally ingested colostrum containing IGF-1 will not have any effect on performance.

Another commonly held view supported by Mero was that the potential effect of orally administered IGF-1 would be maximised by delivering the whey fraction of colostrum to athletes.

However the results have shown that this did not result in improved performance, showing that the prior art in this field has not yet taught a way to change body composition or work capacity by a means of a food composition.

Contrary to the prior art, the Applicants have postulated that the removal of casein proteins and other manufacturing processes used in producing the whey extract (with high levels of IGF-1) studied by Mero could lead to a loss of intact IGF-1 and other factors in the processed colostrum and less availability of potential active components in the gastrointestinal tract. Casein may contribute to enhancement of bioavailability of IGF-1 and other components of colostrum which lead to changed body composition or work capacity at conditions found in the gut.

Accordingly, the present invention also includes a food composition for use in changing the body composition and/or physical work capacity, said food composition including colostrum or a fraction thereof, wherein said fraction includes growth factors and casein. Preferably the casein and growth factors are colostrum derived and have been retained in the colostrum following processing of the colostrum preferably as described below.

Metabolic effects of parenterally administered IGF-1 show that it increases fat utilisation. It is possible that EA in particular will benefit from this by increasing physical work capacity by having a greater ability to utilise fats for energy during exercise. Increased utilisation of fats may lead to increased glycogen sparing and less lactate accumulation, both of which are associated with a reduction in fatigue and improved performance. Therefore, it is preferable that the food composition is for use in changing the exercise performance or physical work capacity for a EA.

Preferably the concentrations of anabolic growth factors such as IGF-1 are at least the concentrations found in normal untreated colostrum. However, they may be higher. Preferably the growth factors will be in a composition that maximise their availability in the gut, and hence their absorption into and through the gut.

The food composition may also serve as a means of increasing growth factors such as IGF-1 levels in the body. IGF-1 and other factors in the colostrum have been implicated in tissue growth and repair. Their anabolic and metabolic effects may also effect the body composition and physical work capacity. However, if the growth factors are destroyed by digestion in the gut after oral administration, the interplay of factors in colostrum may be unable to contribute to the improved changes in body composition and/or physical work capacity.

The food composition may be supplemented with a carrier. The carrier may support the delivery of the colostrum to the subject as described above. The carrier may be any liquid, solid or semi-solid carrier. It may be a carrier selected from the groups including full cream, skim, modified, flavoured milk, yoghurt including natural, flavoured, frozen or drinking yoghurt, tonics, and

sports drinks, other dairy products such as custards, cheese and cottage cheese formulations and ice creams. Semi-solid carriers may be selected from pastes and spreads. Solid carriers may include food bars, biscuits, cereals, food fibres, or any other food.

The food composition may include other supplements beneficial for changing the body composition and/or physical work capacity.

Supplements may be selected from the group including other proteins which may not be found in colostrum, minerals and electrolytes, salts, proteins, amino acids (branched and unbranched), nutrients, lipids, fats, vitamins, carbohydrates (simple and complex), inosine, creatine, HMB, buffering agents and other factors which supplement the diet during training.

Preferably, the minerals may be selected from the group including (but not limited to) calcium, iron, phosphorus, iodine, magnesium, zinc, copper, chromium, molybdenum, and magnesium.

Preferably, the vitamins may be selected from the group including (but not limited to) ascorbic acid (vitamin C), D-Alpha Tocopherol (vitamin E), Niacin (vitamin B3) Riboflavin (vitamin B2), Pantothenic Acid (vitamin B5), Pyridoxine HCl (vitamin B6), Thiamine (vitamin B1), Folic Acid, Cyanocobalamin (vitamin B12), and Cholecalciferol (vitamin D3).

Preferably, the amino acids are selected from the group including (but not limited to) Histidine, Isoleucine, Leucine, Lysine, Methionine, Phenylalanine, Threonine, Tryptophan, Valine, Alanine, Arginine, Aspartic Acid, Cystine, Glutamine, Glutamic Acid, Glycine, Proline, Serine and Tyrosine, and will be chosen to enhance protein synthesis or improve physiological buffering capacity.

Preferably the nutrients are selected from the group including (but not limited to) Biotin, PABA, Choline, Inositol, L-Carnitine, Betaine, and Gamma Oryzanol.

Preferably the salts are selected from the group including (but not limited to) sodium, potassium, and magnesium.

Preferably the carbohydrates are selected from the group including (but not limited to) sucrose, maltodextrose, glucose and fructose.

Preferably the fats are selected from the group including (but not limited to) fat milk solids and vegetable fat. More preferably, fats are retained or reintroduced to the product from the colostrum.

Preferably other factors are selected from the group including emulsifiers such as lecithin, food acids, flavours, preservatives and colourings preferably to improve the delivery and preservation of the food composition.

The food composition may also be provided in any form including a powder, liquid, semi-solid or solid. The food composition may also be delivered as a unit dosage form such as in a tablet, capsule or powder.

In another aspect of the present invention there is provided a method of producing a food composition including colostrum or a fraction thereof including colostrum-derived growth factors maintained therein following fractionation of the colostrum for use in changing body composition and/or physical work capacity, said method including:

providing colostrum prepared by a process including:

subjecting colostrum to an ultra-filtration process to provide an ultra-filtered colostrum retentate;

subjecting the ultra-filtered colostrum retentate to a spray drying process; and

removing the spray-dried colostrum.

The colostrum may be further subjected to a bacterial reduction step preferably utilising centrifugation. The centrifugation may be a flow through centrifugation wherein the centrifugation is performed by controlling throughput and thereby residence time of the colostrum during centrifugation. The centrifugation is preferably performed in conjunction with a low heat treatment (less than 72°C x 15 sec) preferably less than 64°C, thereby retaining the maximum level of bioactivity of active components consistent with food safety requirements.

Standard pasteurisation (72°C x 15 secs) and some other treatments used to reduce contamination or produce colostrum products can destroy or reduce the levels of growth factors and other important bioactive constituents

including immunoglobulins and other factors found in colostrum and/or reduce their stability and bioavailability in the gut.

Accordingly, it is preferable that the colostrum is treated by any process to preserve or to enhance the levels of growth factors and other bioactive proteins, lipids or carbohydrates contained therein. Preferably, the colostrum is processed according to the processes outlined in patents AU668033, AU644468, NZ239466, NZ260568 or PCT/AU96/00708, the contents of which are referred to and incorporated herein.

These processes of treating colostrum may further remove salt and contaminants such as bacteria and somatic cells from the colostrum whilst maintaining the bioavailability as close to that of untreated colostrum preferably including casein in the product. Casein has been shown to enhance the bioavailability of IGF-1 at conditions found in the gut lumen. Accordingly, casein may be added or maintained in the colostrum following the processing of the colostrum. The colostrum may be prepared by the following process:

a) the colostrum from up to the first 6 milkings following calving is collected;

b) the colostrum is warmed to 55°C and skimmed in a standard dairy separator to reduce or standardise fat levels; and/or allow the fat portion to be processed separately prior to reintroduction to the product;

c) the skimmed colostrum is then heated up to 63°C for for a period varying from 15 seconds up to 30 minutes and/or centrifuged at 12,000 *g* in a bactofuge to reduce bioburden and preferably to also improve ability to process downstream;

d) the heat treated skimmed centrifuged colostrum is then either added to fresh dairy or other products ready for consumption with said products acting as a carrier or spray dried ready for consumption or further formulation, or ultra-filtered to reduce water, lactose and electrolyte levels in order to concentrate the protein content or processed in a manner such as ion exhcange chromatography; and

e) the concentrate or eluate is then either added to fresh dairy or other products ready for consumption said products acting as a carrier, or spray dried or processed in a manner such as filtration or UHT, to obtain a long life liquid

(LLL) which can also be freeze or spray dried retaining activity of growth factor proteins.

The spray dried powder or LLL can be included in food or pharmaceutical products or taken as is, or reconstituted by the consumer with any suitable carrier. Fat may be reintroduced prior to spray drying

Preferably the colostrum maintains levels and bioactivity of growth factors similar to that of unprocessed colostrum. The bioactivity can be measured using cell growth assays and making the comparison to untreated colostrum. This may be achieved by utilising the processes outlined in AU668033, AU644468, NZ239466, NZ260568 or PCT/AU96/00708, the contents of which are referred to and incorporated herein. Those processes also maximise the bioavailability of the IGF-1 and other growth factors and immunoglobins by the retention of casein.

In another aspect of the present invention, there is provided a method of changing body composition and/or physical work capacity, said method including administering an effective amount of a food composition including colostrum and a carrier.

Preferably, the food composition is as described above.

The food composition is preferably for use in changing, in a favourable or improved manner, the body composition and/or physical work capacity preferably in subjects wishing to obtain an improvement to the body as described above, athletes, people with physically demanding occupations or pastimes, or patients in a catabolic state/weight loss situation, or experiencing fatigue.

There is also provided a method of increasing tissue mass, said method including administering an effective amount of food composition including colostrum and a carrier.

The tissue may be a tissue selected from the group including connective, epithelial, muscular or nervous tissue. The tissue may be gut tissue or other tissue.

The body composition may change by increasing gut or other tissue mass via an increased synthesis of contractile or non-contractile protein. The

anabolic effects of growth factors such as IGF-1 present in colostrum may lead to these increases if provided in a manner which maximises bioavailability of these factors in the gut. A changing of physical work capacity may result from the increased height or muscular power and strength, or increased metabolic or respiratory buffer capacity, or reduced muscle damage.

Also provided is a method of increasing fat utilisation, said method including administering an effective amount of a food composition including colostrum and a carrier.

An increased muscle mass and increased fat utilisation may result in a changing of body composition which includes an increased lean body mass through increased synthesis of proteins due to the anabolic effects of IGF-1 and/or other colostrum factors. Preferably there is reduced fat mass through increased utilisation of fatty acids due to stimulation of fat metabolism by IGF-1 and/or other factors. However, an increased metabolic rate may also result from an increased fat-free mass (FFM). This is particularly helpful for the PSA but also for those wishing to improve their body by weight loss.

Also provided is a method for increasing height, said method including administering an effective amount of a food composition including colostrum and a carrier.

There is also provided a method of reducing physiological fatigue and/or improving the psychological perception of fatigue, said method including administering an effective amount of food composition including colostrum and a carrier.

A reduction in fatigue and/or perception thereof may contribute to a change in physical work capacity experienced through increased muscle mass, or possibly through increased fat metabolism and increased glycogen sparing resulting in less lactate accumulation, or through an increased capacity to buffer the effect of metabolic acids

Also provided is a method of increasing recovery after exercise said method including administering an effective amount of a food composition including colostrum and a carrier. The increased recovery and/or increased buffer capacity may manifest as an improvement in performance.

There is also provided a method of increasing growth factor and/or other colostrum component levels in the body, said method including administering an effective amount of food composition including colostrum and a carrier.

The increased growth factor or other colostrum component levels may result in a change to the body composition and/or work capacity.

Preferably, the increased growth factor component levels are provided by the colostrum (colostrum-derived). Increases in growth factors in particular may contribute to any of the changes in body composition and/or physical work capacity mentioned herein. Preferably, the growth factors include IGF-1.

The levels of IGF-1 may increase in the body, preferably in the gut. Levels of IGF-1 in the blood have generally been shown not to increase significantly after oral administration. However, maximum bioavailability is achieved by the composition herein described, which has overcome some of the problems of obtaining improved work capacity/body composition.

Despite the commonly held belief that IGF-1 and other macromolecules are quickly digested in the gastrointestinal tract, and that orally ingested growth factors such as IGF-1 are not available systemically, oral administration of colostrum as described above has been demonstrated by the Applicants to result in improvements in body composition and work capacity.

There is also provided a method of treating or preventing a disorder of the gut, said method including administering an effective amount of a food composition including colostrum and a carrier.

A disorder of the gut may be selected from the group including mucositis, gastrointestinal damage from administration of non-steroidal anti-inflammatory or other drugs, gastrointestinal damage from irradiation therapy, gastrointestinal damage from chemotherapy, damage from infection caused by pathogens such as rotavirus, *E. Coli spp, Salmonella spp, Cryptosporidium spp, H. pylori* etc, (eg. in, but not limited, to HIV/AIDS patients), damage from gut surgery, and damage due to disease such as crohn's disease, inflammatory bowel syndrome, coeliac disease or cystic fibrosis.

There is also provided a method of facilitating gut growth and development said method including administering an effective amount of a food composition including colostrum and a carrier.

The use of the food composition may be particularly for use in treatment of short bowel syndrome, massive small bowel resection (MSBR) and/or intestinal adaptation resulting from the residual bowel compensating for a loss in absorptive surface. The treatment may further include the prevention of side effects such as diarrhoea caused by short bowel syndrome, MSBR or intestinal adaptation.

Preferably the food composition for gut growth and development includes colostrum prepared by the processes described above. A preferred dose may be in the order of 1 to 10 g/kg/day.

The treatment may be conducted by using the food composition alone or in combination with other additional growth factors such as Glucagen-like peptide (GLP-2) analogue, and/or Insulin-like growth factor (IGF-1).

In another aspect there is provided a method of increasing buffering capacity, said method including administering an effective amount of food composition including colostrum and a carrier.

The addition of colostrum may buffer against effects of lactic acid in and during exercise. When lactic acid builds up, the food composition may be administered before, during or after exercise as a preventative measure.

In yet another aspect, there is provided a method of reducing effects of metabolic acidosis, said method including administering an effective amount of a food composition including colostrum and a carrier

Again, the presence of a colostrum based food composition may be administered before, during or after exercise or training.

The colostrum may be hyperimmune colostrum from animals vaccinated in order to produce antibodies effective in preventing or treating infectious diseases. Athletes undergoing heavy training programmes are at risk of infections due to lowered immune status and by often travelling.

Endurance athletes sometimes suffer bouts of diarrhoea which are induced by their training. Damage to the intestinal mucosa is known to

increase intestinal permeability and cause diarrhoea [Ford, R.P.K. et al (1986)] and although the precise mechanism of the diarrhoea experienced by endurance athletes is unknown, it is generally accepted that mechanically induced damage to the intestinal mucosa resulting from repetitive compression of the gut during long training sessions increases intestinal permeability and leads to episodes of diarrhoea.

There is also provided a method of reducing muscle damage during exercise, said method including administering an effective amount of a food composition including colostrum and a carrier.

Creatine kinase is present in skeletal muscle, brain tissue and heart tissue and damage to these tissues results in the release of increased levels of creatine kinase into the blood. Plasma creatine kinase concentrations are sometimes elevated during exercise, indicating that the exercise has induced muscle damage. The increased IGF-1 and/or other factors provided in colostrum may contribute to an increase in protein structure of muscle and thereby preventing against injury, or may improve wound repair, thereby contributing to the reduced muscle damage during exercise.

In a preferred aspect there is provided a method of changing body composition and/or physical work capacity said method including administering over an effective period, an effective amount of a food composition including colostrum and a carrier.

Preferably, the food composition is as described above and prepared by the methods outlined above.

The term "effective period" is a period wherein a significant improvement in body composition and/or physical work capacity is noticed. The period may be up to 4 weeks or up to 8 weeks. However, the period may be longer depending on the condition to be improved.

The term "effective amount" will depend on the subject undergoing the improvement and on the bioactivity of the factors in colostrum, and on the bioavailability of those factors in the gut. Preferably, the subject is a PSA or a EA or someone who might benefit from reduced muscle damage, increased physiological buffering capacity, increased height, perception of reduced fatigue

during training, improved recovery and/or performance, improved body composition. For colostrum preferably prepared as described herein, the daily dosage may equate to approximately 0.2-2 g/kg per day. Casein has been shown to be very effective for preserving IGF-1 at conditions found in the gut. Where casein is absent, the equivalent amount of IGF-1 or other factors in colostrum required for an effective amount may be approximately 4 to 5 times the dose.

In determining the dosage of colostrum, consideration should also be given to the quantity of colostrum that could reasonably be consumed for a day. Colostrum powder preferably prepared as described herein may be dissolved in any carrier or liquid, semi-solid or powder form as described above. Skimmed milk or a skimmed milk/water mix may be used so that it can be taken orally as a food drink. 40 g of colostrum powder can be adequately dissolved in 250 mL of skimmed milk/water. It is preferable that the subjects (patients or athletes) be given a dosage of approximately 0.5-1 g/kg per day. Preferably the colostrum has been prepared by the above mentioned processes, preferably for retaining casein in the colostrum.

The colostrum may be delivered to the subject in a single dose or in multiple doses over each period of 24 hours. For example, for a 60 g dosage of colostrum, 20 g of bovine colostrum powder may be provided to the subject in morning and 40 g of bovine colostrum powder may be provided in the evening.

In a further preferred aspect there is provided a method of changing body composition and/or physical work capacity in an athlete, said method including administering to an athlete an effective amount of a food composition including colostrum and a carrier

Preferably the colostrum is prepared as described herein

Preferably, the athlete is a PSA or an EA. The two types of athletes have different demands on their training which leads to differences in the way their bodies adapt.

The changed body composition may be a change measurable by comparing anthropometric measurements over a period of time, preferably over a period of at least 4 weeks, more preferably over 8 weeks. Preferably, the

anthropometric measurements are selected from the group including height, mass, skinfolds, thigh girths, calf girths, leg volumes, and body composition by hydrodensitometry, or plethysmography. Therefore it is preferred that the method is applicable to changing any one of these anthropometric measurements, or a metabolic change such as physiological buffering capacity, or mood state.

The changed physical work capacity may be measured by comparing an athletes performance of a battery of exercises over a period of time, preferably over a period of at least 4 weeks, more preferably, over 8 weeks. Preferably, for a PSA, the battery of exercises may be selected from the group including measuring the effect on a cycle, knee extensions, and/or knee flexions, vertical jump heights and sprint accelerations. Preferably, for an EA, the test battery may be selected from the group including but not limited to measurement of an exercise test more preferably an incremental exercise test to determine total times and/or distances covered to exhaustion, total work done, peak oxygen uptakes, oxygen uptake and heart rates at lactate threshold and respiratory exchange ratios (RER), buffer capacity, and blood lactate concentrations during submaximal exercise.

Therefore, it is preferred that the method is applicable to changing any one of these measurements. Most preferably there is provided a method of improving performance in an EA, said method including administering over an effective period, an effective amount of a food composition including colostrum and a carrier.

Preferably, the colostrum is prepared as described herein.

Also it is preferable to provide a method of reducing serum creatine kinase (CK) levels in PSA or an EA or other person likely to incur muscle damage as a result of exertion or exercise, said method including administering over an effective period, an effective amount of a food composition including colostrum and a carrier.

Preferably the colostrum is prepared as described herein

The reduced levels of serum CK may be a result of reduced muscle damage. Accordingly, there is also provided a method of reducing muscle

damage by administering to an athlete an effective amount of a food composition including colostrum and a carrier.

Administration may be via any route which does not cause side effects to the body. For instance, colostrum contains high levels of proteins which may cause immune responses Therefore, injection is not a suitable means of administration. However, other means including oral, rectal, or dermal administration is suitable providing sufficient colostrum can be delivered to the body.

Administration may be staggered or continuous. By "staggered", it is meant that a dose could be delivered at intervals during the day. By "continuous" the colostrum may be delivered to the body via a pump or other continuous delivery means either to the mouth or directly to the gastrointestinal tract.

During a period of training the food composition including colostrum and a carrier may be administered before and/or during exercise.

Colostrum may be administered after exercise. If hyperimmune colostrum is used, administration before and during exercise could help prevent infection. If administered after, the colostrum could help treat infection and gut damage by combined activity of antibody and growth factors.

The present invention will now be more fully described with reference to the following examples. It should be understood, however, that the description following is illustrative only and should not be taken in any way as a restriction on the generality of the invention described above.

FIGURES

Figures 1A and 1B show that physiological buffer capacity was lower in the Placebo group compared with the Active group during both the first and second rows at week 9 (P=0.02).

Figure 2 shows the difference between the distance covered between an Active and a Placebo group in a maximal rowing test.

Figure 3 shows the difference between the work done between an Active and a Placebo group in a maximal rowing test.

Figure 4 shows a difference in the change in stature between the Active and Placebo group.

Figure 5 shows a difference in fatigue perception between an Active and Placebo group.

Figure 6 shows a difference in fat mass between an Active and Placebo group.

EXAMPLE 1

Testing Procedures to monitor changes in body composition and physical work capacity

A. Growth

1. Body Mass and Stature (height)

Body mass was measured using a set of electronic digital scales (AND Mercury, FV-150). Stature was assessed using a stadiometer (SECA).

2. Resting Blood Pressure (RBP)

RBP was monitored with subjects in a seated position using a manual sphygmomanometer (Accoson MK 2).

3. Thigh and Calf Girths

Thigh and calf girths were measured using a metal tape (Lufkin, W606PM) with subjects standing in the anatomical position. Thigh girths were measured at the midpoint between the greater trochanter and the tibial plateau. Calf girths were measured at the point of greatest circumference.

4. Fat Mass (FM) and Fat-Free Mass (FFM)

FM and FFM were determined by calculating body density (BD) using hydrodensitometry (underwater weighing) according to the following method:

A chair was suspended by a pulley system from a Western Load Cell connected to a linear chart recorder (Rikadenki). The load cell was calibrated using a 5 kg calibration mass. A minimum of 5 underwater trials were conducted at residual volume and the largest value recorded was taken to be

the underwater mass. Water temperature was maintained in the range 30.2° - 36.1° C.

The residual volume was measured by helium dilution using a 10 litre Stead-Wells modular spirometer and helium analyser; 125 mL was subtracted from the functional residual capacity in order to correct for the deadspace of the mouthpiece and the volume of helium absorbed by the blood. The residual volume was measured after the underwater trials. Measurements were recorded whilst the subjects was immersed to neck level and in the same posture as during the underwater trials. BD was then determined from the formula of Goldman and Buskirk , except that no correction was applied for gas in the gastrointestinal tract; percentage body fat (%BF) was then calculated according to Siri.

There was no significant change in residual volume in either group of subjects throughout the duration of the study ($P>0.05$) so the lowest residual volume recorded for each subject was used for the calculation of BD, %BF, FM and FFM.

The coefficient of variation for the determination of BD using the above method was 0.02%.

5. Blood Sampling Techniques

After being underwater weighed the subjects dried themselves and changed into their exercise clothing. A venous blood sample (10 mL) was then taken from the median cubital vein at the elbow of one arm. 6 mL of blood was placed into a plastic tube and allowed to clot in order to obtain serum. The remaining 4 mL was placed into a tube containing dipotassium EDTA as an anticoagulant to obtain plasma. Both tubes were then centrifuged for 10 min at a relative centrifugal force of 2000 *g* at 4°C in a refrigerated centrifuge (Beckman, GS-6R). The serum was then drawn off and divided evenly amongst 3 plastic test tubes and frozen at –20°C for subsequent analysis of serum creatine kinase (CK) concentrations in triplicate (see below). The plasma was drawn off and 1 ml was frozen at –20°C for subsequent analysis of plasma IGF-1 concentrations (see below), whilst the remainder was frozen at -

20° C in a plastic test tube and retained in case subsequent analysis proved necessary.

6. Determination of Plasma IGF-1 Concentrations

The plasma concentrations of IGF-1 in each sample were measured three times by radioimmunoassay after separation of their binding proteins by high performance size exclusion liquid chromatography at pH 2.5 according to the method as modified by Owens et. al. 1990; 1994. The mean of the three assays of each sample was taken as the plasma concentration.

This procedure provided an average within-assay coefficient of variation of 10% and a between assay coefficient of variation of 16%.

7. Determination of Serum Creatine Kinase Concentrations

The serum concentrations were measured in triplicate with an Hitachi 917 automatic analyser using a zero order kinetic assay. The mean of the triplicate assays was taken as the serum concentration.

The coefficient of variation for this assay was 2.4% at 172 U/L and 1.2% at 485 U/L.

B. Supplement Preparation

The bovine colostrum used as the supplement in the present study was prepared according to the patented processes as outlined in Australian Patents 644468, 668033 and New Zealand Patents 239466, 260568 the contents of which are incorporated herein by reference.

The colostrum from up to the first six milkings following calving was collected.

The colostrum was warmed to 55°C and skimmed in a standard dairy separator to reduce fat.

The skimmed colostrum was then heat treated at no more than 63°C for no more than 30 min and/or centrifuged at 12, 000 *g* in a Bactofuge to reduce bioburden.

The pasteurised colostrum was then ultrafiltered to reduce water, lactose and electrolyte levels in order to concentrate the protein content.

The concentrate was then spray dried in an aseptic, pharmaceutical model 2 stage spray drier with a filtered air supply to produce colostrum powder (powder production accords with the Code of Good Manufacturing Practice for Therapeutic Goods in Australia).

The supplements were mixed with skimmed milk/water and taken orally.

The placebo used in the study was whey protein concentrate (Alacen 372, New Zealand Dairy Corporation).

The supplements were provided in 20 g sachets and the subjects consumed the contents of one sachet (20 g) each morning with their morning meal, and two sachets (40 g) with their evening meal. Each subject prepared the powder for consumption in the following manner:

Each 20 g sachet of powder was added to 85 mL of warm water and mixed thoroughly;

40 mL of skim milk was then added for each 20 g of powder and the mixture was shaken until well mixed.

If desired the mixture was refrigerated until chilled before drinking, or it could be drunk warm.

EXAMPLE 2

Effects of oral colostrum supplementation on Endurance Athletes (EA) - Running Performance

The following study was conducted to determine whether bovine colostrum has favourable effects on running performance in Endurance Athletes (EA). For the present study, bovine colostrum powder as prepared above was used as a supplement in the food composition ingested by the athletes.

The purpose of this study was to determine whether the oral administration of 60 g per day of bovine colostrum powder (intact™) was more effective than the administration of 60 g per day of whey protein powder in:

1) improving endurance running performance
2) reducing body fat

3) reducing exercise induced muscle damage

The present study employed a double-blind, placebo controlled, parallel, randomised design to determine the effect of supplementation with a low fat, low lactose, concentrated bovine colostrum protein powder (intact™, NorthField Laboratories Pty Ltd) on plasma IGF-1 concentrations and endurance running performance. After an initial familiarisation period in the two weeks prior to commencement, 39 males, aged 18-35 years, completed an 8 week running program (3 x 45 minutes/week at lactate threshold) whilst consuming 60 g/day on intact™ bovine colostrum (n=23, peak VO_2 53.5 ± 1.1 $ml.kg^{-1}$ min^{-1}) or whey protein (n=16, peak VO_2 54.2 ± 1.7 $ml.kg^{-1}$ min^{-1}). All subjects followed dietary guidelines provided by the researchers and kept food diaries throughout the study period for subsequent dietary analysis. Subjects completed 2 incremental treadmill running tests to exhaustion (10 km/hr, incremented 1% grade every 3 min) separated by 20 minutes of recovery at weeks 0, 4 and 8. There were no differences in plasma IGF-1 concentrations between the groups at week 0 (colostrum 231.1 ± 10.7 ng/ml, placebo 221.0 ± 13.3 ng/ml; P=0.37). Plasma IGF-1 concentrations did not change in either group during the study period (P=0.90). There were no differences in the distance covered (m) or work done (kJ; vertical distance covered x body mass x 9.81 m/s^2) during the first (colostrum 4649 ± 238 m, 155.8 ± 15.7 kJ; placebo 4464 ± 320 m, 140.2 ± 19.6 kJ; P>0.46) or the second (colostrum 4044 ± 357 m, 120.6 ± 21.3 kJ; placebo 3942 ± 388 m, 110.7 ± 21.1 kJ; P>0.91) treadmill runs at week 0. Distance covered and work done during the first treadmill run increased in both groups during the study period (P<0.01), but at similar rates (P>0.69). During the second treadmill run both groups exhibited similar increases in the distance covered and work done from weeks 0-4 (P>0.20) but, from weeks 4-8 the intact™ colostrum group continued to improve whilst the performance of the placebo group plateaued, such that by week 8 the colostrum group ran further (colostrum 4662 ± 251 m, placebo 4237 ± 323 m; P=0.04) and did more work than the placebo group (colostrum 150.7 ± 17.1 kJ, placebo 124.2 ± 18.9 kJ, P=0.03) The TEM for running time (which equates to distance covered and work done) was 2%. There were no differences in dietary intakes between two

groups. These results indicate that oral supplementation with intact™ bovine colostrum improves the ability to perform a second bout of maximal exercise following a relatively short period of recovery from a prior bout of maximal exercise.

This study confirmed significantly enhanced ability to run and work *after* the rest period. Strong trends are shown towards less muscle damage as measured by creatine kinase.

In a study that measured fat mass and fat free mass, post-hoc analysis showed that fat mass had decreased significantly in the active group (P=0.005) but not in the placebo group (P=0.08) by Week 8.

Overall there was also a trend to reduced fat mass despite the intact™ colostrum group having started the test period with lower fat mass % than the placebo group (see Figure 6).

Throughout the period of the study there was a trend for the athletes taking the colostrum supplements to increase the distance covered during the first of the two treadmill runs at each trial. However, the athletes taking the colostrum supplement did demonstrate significantly greater increases in the distance covered and the amount of work done during the second treadmill runs at each trial. As a result of the greater increase in the work done during the second treadmill runs at each trial there was also a significantly greater increase in the total work done during both runs at each trial in the colostrum group.

In some cases, the finding of no significant difference in performance between the two groups during the first treadmill run at each trial (although there was a trend suggesting that performances were improved) but a significantly greater improvement in the colostrum group during the second run suggests that although there may be some performance enhancing effect of colostrum supplementation, there is apparently a greater effect in terms of improving recovery from previous exercise. The mechanism for this enhanced recovery is not immediately apparent from the data collected in the present study since there were no differences in blood lactate or RER responses during the second treadmill runs between the two groups at any of the trials. There

was however, a trend for the CK values to be less elevated at the end of each trial in the colostrum group and it is possible that a reduced level of muscle damage caused in the first treadmill run could have assisted the subjects on the colostrum supplement in sustaining performing better in the second treadmill run. However, it cannot be ruled out that some other parameter which was not measured could have led to the greater improvement in these subjects.

There was no change in plasma IGF-1 concentrations in response to taking bovine colostrum supplements, despite the fact that it has been shown that orally administered ^{125}I-IGF is transported into the circulation in calves

In summary, this study provides evidence that oral supplementation with bovine colostrum can enhance increases in endurance capacity and body composition beyond those which will ordinarily be achieved through training alone.

EXAMPLE 3

Effects of oral colostrum supplementation on Endurance Athletes - Elite Rowing Performance (female)

The following study was conducted to determine whether bovine colostrum has favourable effects on rowing performance in Endurance Athletes. Bovine colostrum powder as prepared above was used as a supplement for the food composition ingested by the athletes.

(a) Physiological Buffer Capacity

Results in Figures 1A and 1B show that colostrum had a protective effect on buffer capacity during a second row Physiological buffer capacity was lower in the placebo group during the first and second rows at week 9 (P=0.02). This was due to a tendency for an increase in buffer capacity in the Active group and a decrease in the Placebo group such that there was a significant difference in the change in buffer capacity between the two groups (P=0.05).

The Active group also demonstrated an ability to maintain or enhance their capacity to buffer against the effects of lactic acid in blood pH by week 9 of

the study during rowing exercise (P=0.05) such that their blood pH dropped less for a given increase in lactic acid concentrations.

A lesser ability to buffer effects of lactic acid may result in an increased susceptibility to fatigue. Hence the placebo group did not perform as well as the active group.

Buffer capacity is calculated from the relationship between blood lactate and pH and represents the drop in pH per unit increase in lactate. Buffer capacity reflects the ability of the body's buffer systems to counteract the pH decreasing effects of lactic acid.

(b) **Exercise Performance Improvement**

Results in Figures 2 and 3 demonstrate that the active group had a significantly greater improvement in distance covered (P=0.05) and work done during a maximal rowing test.

(c) **Growth**

The subjects on the colostrum grew more than those on the placebo. The Active group were taller than the Placebo group at week 0 (Active 176.5 ± 1.1.cm, Placebo 172.5 ± 1.65 cm; P=0.0002) but grew more than the Placebo group during the study period (P=0.02). The greater increase in height could not be accounted for by either the initial height (r^2=0.06, P=0.53), nor the age (r^2=0.06, P=0.54) of the subjects at week 0. Results are shown in Figure 4.

The results point to growth factors being absorbed from the colostrum and opens up possibilities for further studies into growth promotion in children.

(d) **Fatigue Perception**

Psychological perception of fatigue as determined using a Profile of Mood States (POMS) questionnaire remained relatively stable during the first 5 weeks of study, but during the final 4 weeks the observed increase in fatigue perception was attenuated in the Active group (P=0.05). Results are shown in Figure 5.

In summary, rowers ingesting intact™ colostrum demonstrated:

- improved ability to perform a maximal workload;

- a significant improvement in physiological buffering capacity (measured in blood samples) during the second rowing exercise after the rest period, which is not explained by bicarbonate levels. The difference in buffering capacity is a new finding that help to explain the performance improvements being seen, and has potential to benefit anyone with a need to cope with metabolic acidosis (sports due to lactic acid, other causes of acidosis);

- a significantly greater increase in height during the study period. This is a new finding which is unexpected, as it against suggests that there is a systemic effect of taking intact™ over and above the nutritional benefit of the placebo

- a perception of less fatigue during training as measured by a Profile of Mood States (POMS) questionnaire.

EXAMPLE 4

Effects of oral colostrum supplementation on Power/Strength Athletics - Vertical Jump, Peak power and force

The following study was conducted to determine whether bovine colostrum has favourable effects on vertical jump, peak power and peak force performance in Power Strength Athletes (PSA). For the present study, bovine colostrum powder as prepared above was used as a supplement in the food composition ingested by the athletes.

The present study employed a double-blind, placebo controlled, parallel, randomised design to determine the effect of 8 weeks of supplementation with bovine colostrum powder (intact™, NorthField Laboratories Pty Ltd) on plasma IGF-1 concentrations and a number of functional measures of muscle power output.

After an initial familiarisation period in the two weeks prior to commencement, 51 males. aged 18-35 years, completed an 8 week resistance and plyometric training program (6 days per week) whilst consuming 60 g/day

of intact™ bovine colostrum (n=26) or whey protein (n=25). All subjects followed dietary guidelines provided by the researchers and kept food diaries throughout the study period for subsequent dietary analysis. Subjects performed a battery of four exercise tests twice at weeks 0, 4 and 8 of the study, with each performance of the test battery separated by 20 min of recovery. The test battery consisted of 3 x 20 m sprints, 3 x 10 second bouts of maximal cycle exercise (MCE), 3 x maximal vertical jumps (VJ) and 3 x maximal knee extensions (KE) and knee flexions (KF) on an isokinetic dynamometer. The best of the 3 attempts at each exercise was recorded for each performance of the test battery.

There was no difference in plasma IGF-1 concentration between the groups at week 0 (colostrum 255.8 ± 15.5 ng/ml, placebo 259.7 ± 23.0 ng/ml; P=0.87) and plasma IGF-1 did not change in either group during the study period (P=0.58). The training volumes completed by each of the two groups were the same for both the resistance (P=0.37) and plyometric programs (P=0.57). By week 8 the colostrum group had improved their VJ significantly more than the placebo group during both the first (colostrum 3.0 ± 0.6 cm, placebo 1.3 ± 0.7 cm; P=0.004) and second (colostrum 2.5 ± 0.6 cm, placebo 0.8 ± 0.7 cm; P= 0.002) performances of the test battery. There were also trends for the colostrum group to exhibit greater improvements in absolute and relative peak power outputs during MCE (P=0.09) and peak force generated for KF (P=0.07). Creatine kinase (CK) activity tended to increase less in the colostrum group (P=0.14), particularly during the first 4 weeks of the study (P=0.06).

These results indicate that oral supplementation with intact™ bovine colostrum facilitates a greater improvement in maximal power output in response to the same training program. Some of the greater performance improvement may be attributable to a reduction in muscle damage.

This study confirmed significantly enhanced ability to perform vertical jump and trends to improve peak power and peak force. There was a strong trend towards reduced muscle damage as measured by creatine kinase.

The principal finding of the present study was that in athletes undertaking a power training program oral supplementation with bovine colostrum prepared as above resulted in a significantly greater increase in vertical jumping performance than was achieved using an oral protein supplement.

The only other study which has investigated the effect of bovine colostrum supplementation on the expression of muscle power [Mero, A. et al (1997)] found that colostrum supplementation resulted in a significant difference in serum IGF-1 concentrations, but had no effect on muscle power, as measured using vertical jump displacement. The active component in bovine colostrum which is most likely to increase muscle power is IGF-1, since this hormone is known to have anabolic effects on skeletal muscle [Fryburg D.A. et al (1995); Tomas, F.M. et al (1991) (a) and Tomas, F.M. et al (1991)] However, despite reporting a significant difference in serum IGF-1 concentrations, Mero et. al. found no improvement in vertical jumping performance. In the present study the reverse was true, no detectable increase in plasma IGF-1 concentrations were observed, but there was a significant improvement in vertical jumping performance.

During the study there was no significant increase in pre-exercise serum CK concentrations indicating that the training did not induce significant amounts of muscle damage in either group. However, despite the lack of statistical significance there was a trend for serum CK values to increase in the placebo group, but not in the colostrum group

In summary, colostrum prepared as above significantly improved vertical jumping performance in PSA.

EXAMPLE 5

Effects of oral colostrum supplementation on Pigs - growth of gut and body

Growth factors are present in relatively high quantities in colostrum and play an important part in gut development. Gut development and growth in the

piglets is integral to efficient nutrient absorption and protection against bacterial invasion. The growth factor content of milk decreases with advancing lactation and so the opportunity exists to enhance gut growth and development through supplementation with exogenous growth factors. This is particularly pertinent given that the pig gut is relatively immature at weaning and the pig suffers a growth check at or around this time. Recent data has shown that systemic treatment of both by artificially rearing pigs with growth factor analogues increases liver weight and gut growth and development. However, if orally consumed, growth factors may be destroyed by digestion.

Piglet growth can also be limited by the amount of milk they obtain from the sow. Recent research has shown that piglets allowed to consume cows milk *ad libitum* grow approximately twice that of suckled piglets (230 vs 450 g/d). Therefore, early weaning combined with artificial rearing or creep feeding may be a means of increasing piglets growth.

Diets

Two diets were used in this experiment - one containing intact™ colostrum protein concentrate (NorthField Laboratories) prepared by the process of Example 1 and the other, a whey protein concentrate. The diets were formulated to contain equal levels of crude protein and amino acids. It was assumed that the availability of amino acids in the whey protein concentrate and the colostrum protein were equal. The diets were protein deficient so that the efficacy of any growth factors would be clearly demonstrated. Lactose and oil was being kept relatively constant in the diets.

To prepare the diets, the butter, oil and water were heated to 70°C. All dry ingredients were then added to the water and mixed together with 1 ml of anti-foaming agent The melted butter and oil was then mixed with the water. To ensure even distribution of the oil throughout the mix, the milk supplement was homogenised.

Following homogenisation, the vitamins and minerals were mixed into the supplement and it was frozen until required.

Pigs

Sixteen large white male and female piglets were weaned from sows at one day of age. Piglets were allocated to one of two diets based on eight pigs per diet (4 male, 4 female). Piglets were identified with coloured ear tags.

Piglets were trained over two days to suck the liquid diets from a lambar teat. The diets were offered *ad libitum* and represented the only source of nutrients and fluids (i.e. no additional water was supplied). The liquid diets were always fresh and were replaced twice per day. Milk intake and rejects was recorded twice daily. Piglet weights were recorded weekly.

The pigs were offered their diets until they were four weeks of age. At this time 6 males and 6 females from each treatment were euthanased and the gut contents emptied. The weight of the full gut, empty stomach, empty small intestine, empty caecum and empty large intestine were recorded. Small intestine and large intestine lengths were measured. Heart and lung, liver and spleen weights were also recorded.

Results

Growth rates and feed conversion ratio

Addition of the intact™ colostrum to a sows milk supplement significantly improved ($P<0.01$) the four week weight and overall growth rate of piglets from birth to four weeks of age compared to those fed a sows milk supplement containing whey protein.

Significant differences in overall growth rate were not evident until week three of the experiment although the piglets fed sows milk supplement containing intact™ colostrum had a significantly higher growth rate for weeks two and three respectively

Addition of the intact™ colostrum to a sows milk supplement significantly improved ($P<0.05$) the overall feed conversion ratio of piglets from birth to four weeks of age compared to those fed a sows milk supplement containing whey protein.

Intestine length

Addition of the intact™ colostrum resulted in a significant increase in the total intestine length ($P<0.05$), small intestine length ($P<0.05$) and large intestine length ($P<0.0.1$). Piglets fed the sows milk supplement containing the intact™ colostrum had a significantly ($P<0.05$) lower small intestine length relative to the whole intestine length and a significantly higher ($P<0.05$) large intestine length relative to the whole intestine length.

Digestive tract weights

Piglets fed the sows milk supplement containing the intact™ colostrum had a significantly higher ($P<0.05$) full gut weight, empty gut weight, stomach weight, small intestine weight and large intestine weight compared to piglets fed a sows milk supplement containing whey protein.

The ratio of large intestine weight to empty gut weight was significantly increased ($P<0.01$) in piglets fed the sows milk supplement containing the intact™ colostrum.

The ratio of empty gut, stomach, small intestine, caecum and large intestine to empty-body-weight respectively was not significantly different ($P>0.05$) between piglets fed sows milk supplements containing either the intact™ colostrum or the whey protein concentrate.

Organ weights

Liver weights were significantly higher ($P<0.05$) in piglets fed the sows milk supplement containing the intact™ colostrum. No significant differences were detected ($P>0.05$) between the weight of the heart and lungs and the spleen and the relative proportions of all organs to the empty body weight.

Discussion

Growth rates and gut development in piglets were promoted from birth to four weeks of age by the addition of the intact™ colostrum to a sows milk supplement. As the intact™ colostrum was compared with a whey protein concentrate in diets that were formulated to contain equal levels of crude protein and amino acids, it is likely that the improvement growth was due to the

activity of growth factors present in the colostrum prepared as in Example 1. The activity of these growth factors may be confirmed by analysis of blood samples taken during the course of the experiment.

The growth rates observed were similar to those reported previously for piglets suckling the sow and significantly less than those observed for piglets offered cows milk *ad libitum* (450 g/day). As the sows milk supplements used in this experiment were offered *ad libitum*, it can be concluded that the diets were highly protein deficient. This is likely to have contributed to the expression of the growth factors present in the intact™ colostrum. Despite the low protein content of the supplements, the ability to achieve a four week weight of 8.1 kg or greater would be highly valued by the commercial pig industry.

The increase in the empty gut, stomach, small intestine and large intestine weight can be largely attributed to the greater body weight of these piglets. The enhanced development of the large intestine in piglets fed the intact™ colostrum, however, would give these piglets a greater ability to adapt to solid diets with a significantly higher fibre content. This in turn would reduce the post-weaning check observed when piglets are weaned from liquid to solid feed.

Improvements in FCR in piglets fed the intact™ colostrum are likely to be due to the increased size of these piglets and a greater gut capacity. The absolute increase in liver weight is likely to be due to a greater body weight in pigs fed the intact™ colostrum rather than due to dietary influences. Had the growth factors in the isolate had any effect on liver size and function, it is likely that we would have observed an increase in the proportion of liver weight to empty body weight.

Finally, it is to be understood that various other modifications and/or alterations may be made without departing from the spirit of the present invention as outlined herein, and that these results will have application in patient groups outside athletes such as, but not restricted to, infant nutrition, catabolic states, gut growth and development diseases of the gut, short stature metabolic acidosis, gut health repair and fatigue, including chronic fatigue syndrome.

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CLAIMS:

1. A food composition for use in changing body composition and/or physical work capacity, said food composition including colostrum or a fraction thereof wherein said fraction includes colostrum-derived growth factors maintained therein following fractionation of the colostrum.

2. A food composition according to claim 1 further including casein.

3. A food composition according to claim 1 or 2 wherein the growth factor is IGF-1.

4. A food composition according to claims 2 or 3 wherein said casein is colostrum-derived and maintained therein following fractionation of the colostrum.

5. A method of producing a food composition including colostrum or a fraction thereof including colostrum-derived growth factors maintained therein following fractionation of the colostrum for use in changing body composition and/or physical work capacity, said method including:

providing colostrum prepared by a process including:

subjecting colostrum to an ultra-filtration process to provide an ultra-filtered colostrum retentate;

subjecting the ultra-filtered colostrum retentate to a spray drying process; and

removing the spray-dried colostrum.

6 A method according to claim 5 further including a bacterial reduction step including centrifuging the colostrum in a flow-through centrifuge wherein the centrifugation is performed by controlling throughput and residence time of the colostrum during centrifugation.

7 A method according to claim 6 further including combining the centrifugation with low heat treatment by subjecting the colostrum to less than 72°C.

8. A food composition prepared by the method according to any one of claims 5 to 7.

9. A food composition according to claim 8 further including casein.

10. A food composition according to claim 9 wherein the casein is colostrum-derived following fractionation of the colostrum.

11. A method of changing body composition and/or physical work capacity, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

12. A method of increasing tissue mass, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

13. A method of increasing fat utilisation, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

14. A method of reducing physiological fatigue and/or physiological perception of that fatigue, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

15 A method of increasing height, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

16. A method of increasing recovery after exercise, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

17. A method of treating or preventing a disorder of the gut, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

18. A method according to claim 17 wherein the disorder of the gut is selected from the group including mucositis, gastrointestinal damage from administration of non-steroidal anti-inflammatory drugs, gastrointestinal damage from irradiation therapy, gastrointestinal damage from chemotherapy, damage from infection in normal and in HIV/AIDS patients caused by pathogens selected from the group including rotavirus, *E. Coli spp*, *Salmonella spp*, *Cryptosporidium spp*, *H. pylori* , damage from gut surgery, and damage due to disease such as crohn's disease, inflammatory bowel syndrome, coeliac disease, or cystic fibrosis.

19. A method of reducing muscle damage during exercise, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

20. A method of increasing physiological buffering capacity, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

21. A method of improving gut growth and development, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

22. A method of treating short bowel syndrome, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

23. A method of improving vertical jump performance, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

24. A method of improving the ability to generate peak power and peak force, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

25. A method of increasing endurance exercise performance, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

26. A method of reducing fat mass, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

27. A method of improving the bioavailability of components in colostrum which lead to changed work capacity and/or body composition, said method including administering an effective amount of a food composition according to any one of claims 1 to 4 or 8 to 10.

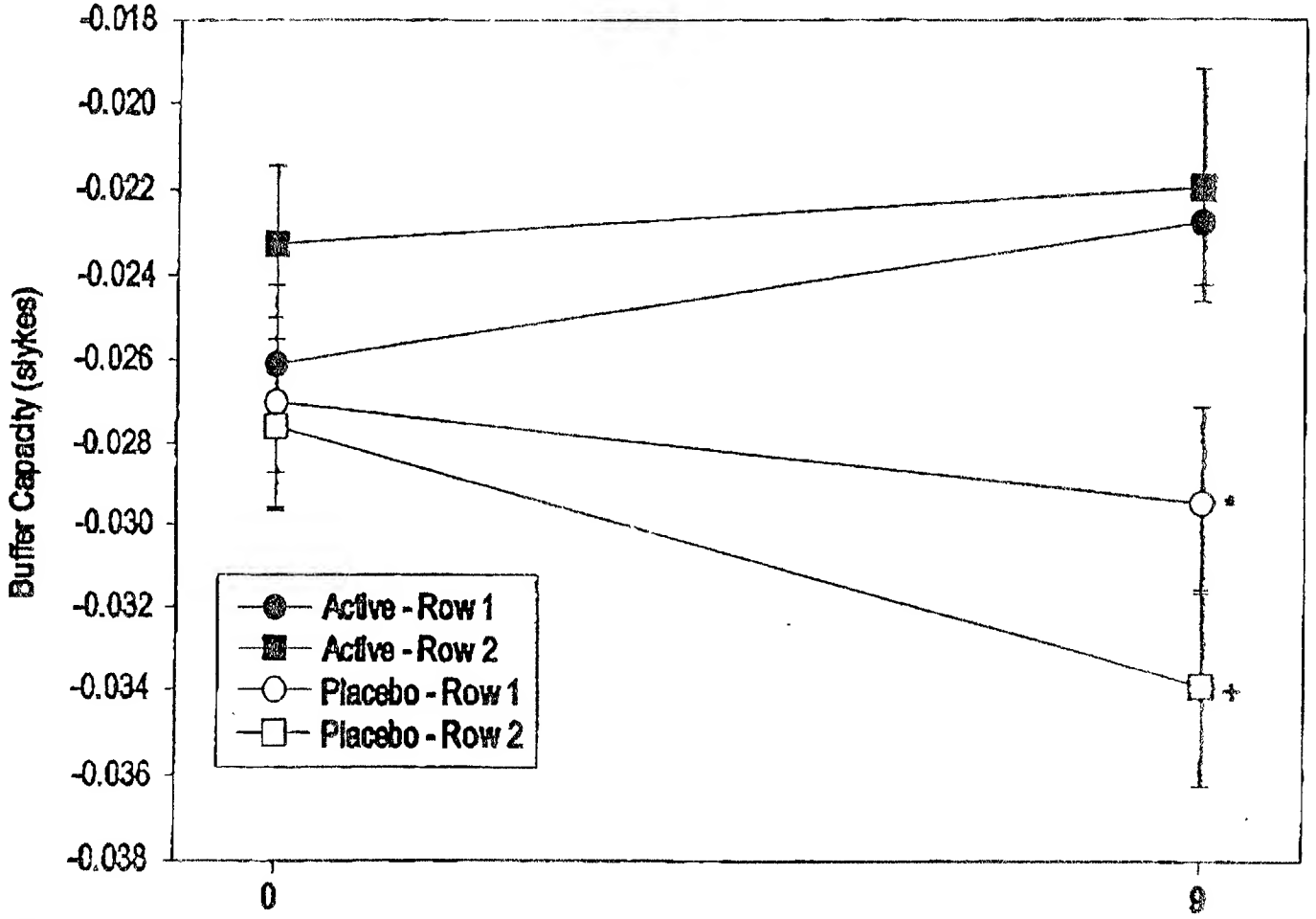
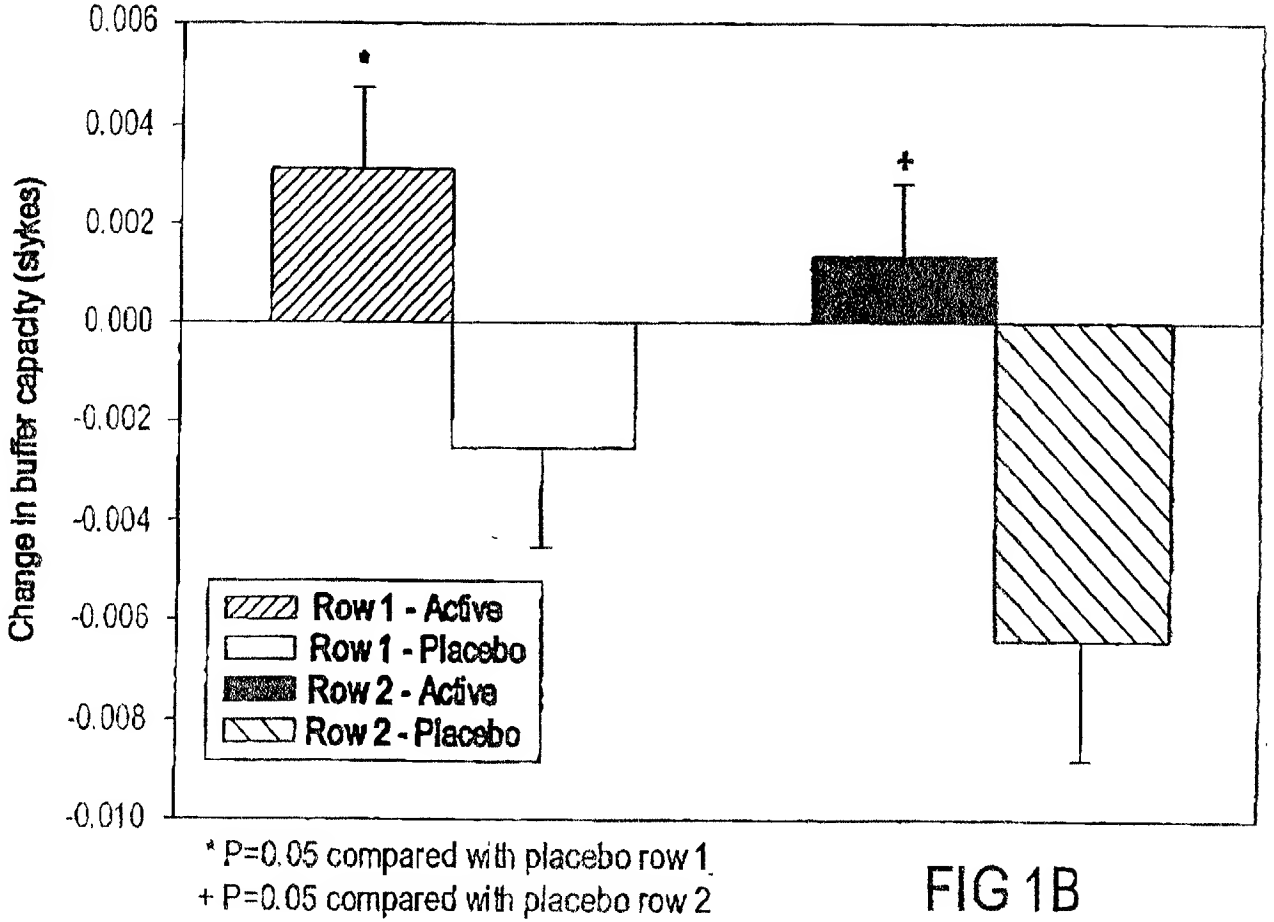


FIG 1A

* P=0.02 compared with active row 1

+ P=0.02 compared with active row 2



* P=0.05 compared with placebo row 1
+ P=0.05 compared with placebo row 2

FIG 1B

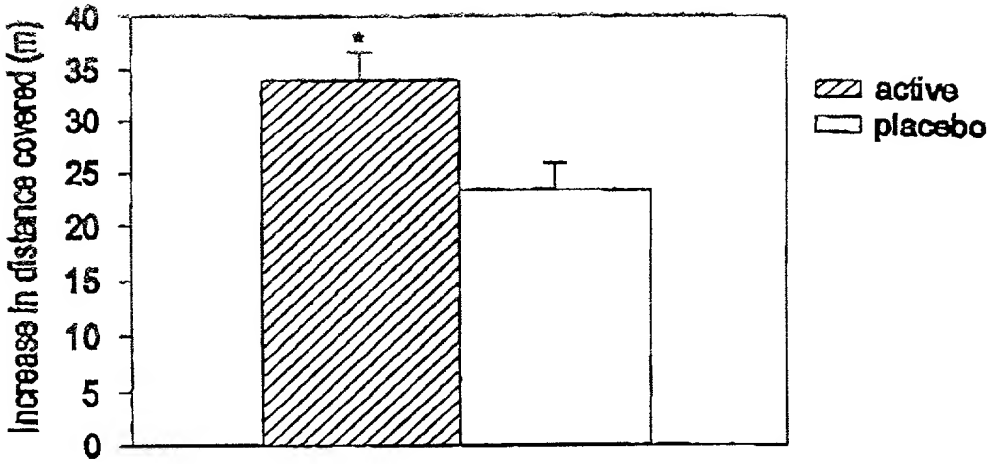

Increase in distance covered (m)
40
35
30
25
20
15
10
5
0
*
active
placebo

FIG 2

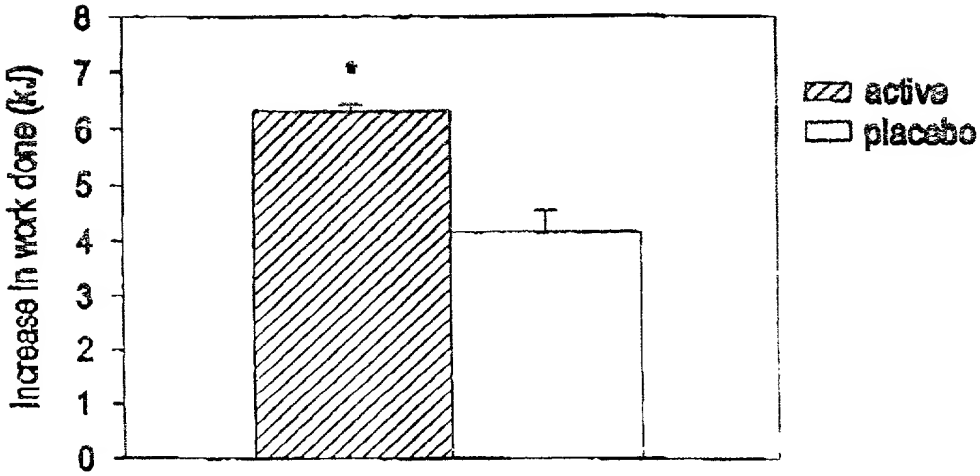

Increase in work done (kJ)
8
7
6
5
4
3
2
1
0
*
active
placebo

FIG 3

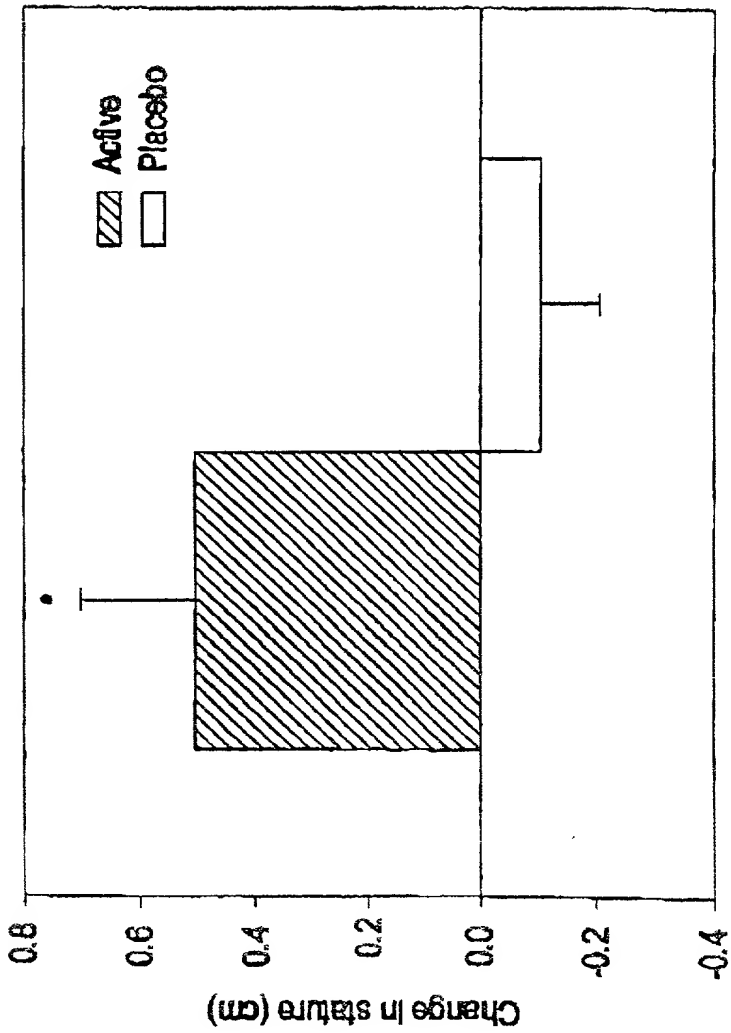


FIG 4

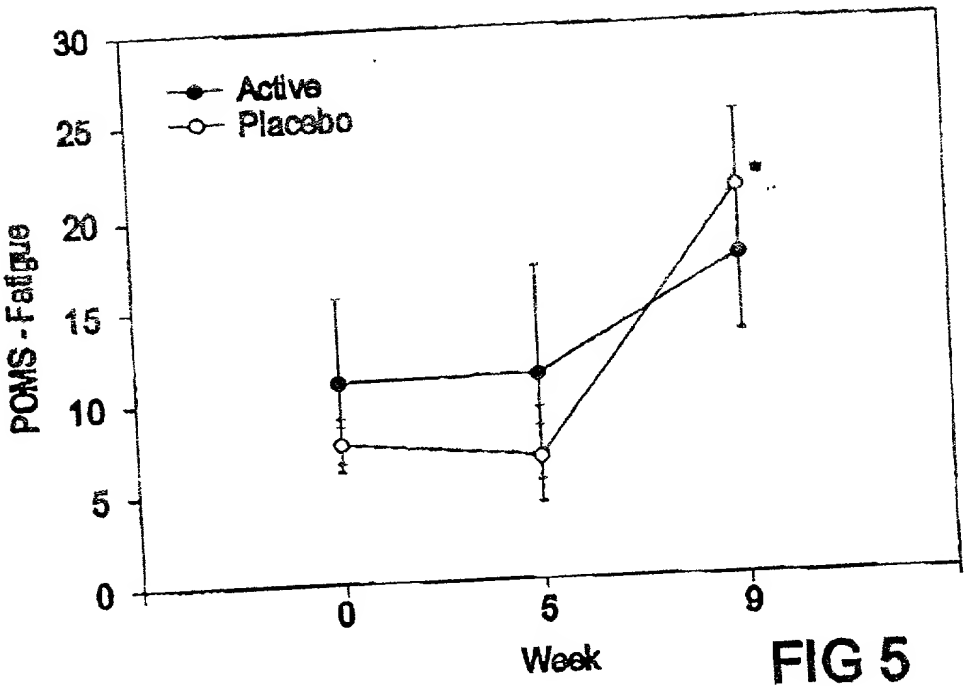

30
25
20
15
10
5
0
POMS - Fatigue
Active
Placebo
*
0
5
9
Week

FIG 5

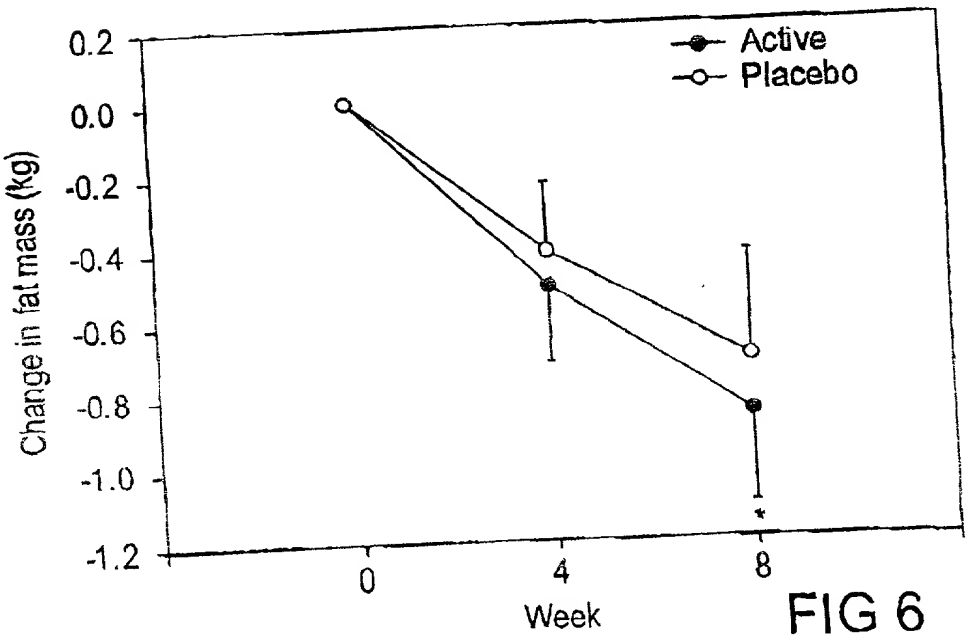

0.2
0.0
-0.2
-0.4
-0.6
-0.8
-1.0
-1.2
Change in fat mass (kg)
Active
Placebo
*
0
4
8
Week

FIG 6